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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,408	10/01/2003	Gilbert Rene Gonzales	PEDE-13	8069
26875 7590 12/04/2009 WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202				
			EXAMINER SAMALA, JAGADISHWAR RAO	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 12/04/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/676,408

Applicant(s)

GONZALES ET AL.

Examiner

JAGADISHWAR R. SAMALA

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-36 and 47-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-36 and 47-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of Applicant's Arguments and Remarks filed on 08/13/2009.

- Claims 27-36 and 47-50 are pending in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 32-36 and 47-50 rejected under 35 U.S.C. 102(b) as being anticipated by Schobel (US 4,687,662) **are withdrawn** in view of Applicant arguments filed on 08/13/2009

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27-36 and 47-50 are rejected under 35 U.S.C.103(a) as being unpatentable over First et al (US 2003/0235613 A1) in view of Wehling et al (US 5,223,264) are maintained for reasons of record in the previous office action filed on 04/13/2009.

Applicant argues that Wehling does not include both (1) a gas-dispersing component including a solid matrix having at least one first gas contained therein, and (2) a gas-generating effervescent component including components reactive with an aqueous vehicle to generate a second gas.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413,208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In this case, The Wehling patent is relied upon to show that it is known in the art an oral administration of pediatric dosage form comprising a mixture of at least one effervescent disintegration agent (reads on gas-generating effervescent

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component), and a pediatrically effective amount of active ingredient, wherein said mixture is present in the form of a compressed tablet and wherein said effervescent disintegrating agent is present in a amount which is effective to both aid in rapid disintegration of said tablet and to provide a positive organoleptic sensation to children, While First patent shows an equivalence that is recognized in the art for an oral administration comprising an active ingredient and a pressurized gas (reads on gas-dispersing component) being trapped in cavities within a pharmaceutically acceptable material in a manner that allows its escape upon dissolution.

Applicant argues that First does not disclose any amounts of water or other liquids that are used with oral administration forms it describes.

This argument is not persuasive since during the preparation of gasified oral administration forms (fructose, lactose and liquid glucose were melted), typically the quantity of water necessarily present will be about 1 to 5 % and fusible sugars containing these amounts of water may be said to be substantially anhydrous. Further, an oral administration form, is an administration form, the swallowing of which is permissible. Such an administration form is usually intended to be given through mouth with small amounts of water, for swallowing, for treating the mouth cavity etc

Applicant also argues that First does not disclose that any release of the first gas occurs then.

This argument is not persuasive since First teaches that the escape of gas does not only produce a pleasant sensation but may also stimulate saliva

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production, thereby providing additional saliva to aid dissolution in the mouth.

Similarly, it may be used to enhance dissolution of tablets or powders in a drinking liquid. Such tablets may be useful for the elderly or swallow-problem population (0018).

Applicant argues that even if the compositions of First and Wehling combined (and Applicant do not acknowledge that a person of ordinary skill in the art would combine First and Wehling), they would not satisfy all limitations of independent claims 27 and 47.

1. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the First and Wehling references are combined to provide an oral administration forms comprising an active ingredient and a pharmaceutically acceptable material trapping pressurized gas within cavities thereof and processing the mixture to obtain an administration form, that permits said gas to escape upon dissolution or shattering of the administration form. The essence of dispersing a first gas and the gas generating component that reacts to produce second gas, and both gases of which are released into the liquid vehicle, will enhance distribution and dispersion of the medicament to form a

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clear solution. Further, children readily accept the oral administration form, not only because the effervescent disintegration agent provides for the controlled and rapid disintegration of the tablet when placed in the mouth or because the effervescent disintegration agent, by its action, aids in the masking of the potentially objectionable tastes of the active material.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8:30 A.M to 5:00 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jagadishwar R Samala/
Examiner, Art Unit 1618

/Jake M. Vu/
Primary Examiner, Art Unit 1618